

University of Maryland College Park

Project Title	Contagious Phenotypes of Acute Respiratory Infection: Identification, Characterization, and Biomarkers {Characterizing and Tracking College Health (CATCH) – the Virus Study}
Purpose of the Study	This research is being conducted by Donald Milton, MD, DrPH and a team of researchers at the University of Maryland (UMD) with funding from the U.S. Defense Advanced Research Projects Agency. We are inviting you to participate in this research project because you are a UMD college student, faculty, or staff member or a household contact of such a person and you live within approximately 3-5 miles or a 15-minute drive of the College Park campus. The purpose of this research project is to identify biomarkers (measurable substances within a person) that can indicate which individuals, when exposed to viruses and bacteria that cause Acute Respiratory Infections (ARI), are likely to become contagious and spread the ARI to others, and to improve our understanding of how ARI are transmitted so that we may better prepare to mitigate or prevent future epidemics and pandemics of influenza and other ARIs.
Procedures	<p>BASELINE QUESTIONNAIRE</p> <p>If you are age 18 or older and you agree to participate in this study you will be asked to complete an online survey or answer an identical questionnaire in person. All of your answers will be recorded directly into a secure electronic study database. We will ask you to provide your name, email address, phone number, social media information, and your preferred method of contact, so that we can contact you during the study. We will ask you to provide basic information about yourself such as your date of birth, sex, race and ethnicity. We will ask you some questions about your medical history, influenza vaccinations, respiratory symptoms and medications, stress, and your habits regarding sleep, exercise, smoking, and alcohol use. We will ask you to provide your dorm room number or local address, and time spent in certain locations on campus (particularly dorm rooms where sensors have been placed to measure CO₂, temperature, relative humidity, and particle matter), so that we can assess your exposure to indoor air and exhaled breath from other building occupants in these locations. We estimate it will take you approximately 10-15 minutes to enter your data and answer the questions in the database.</p> <p>OPPORTUNITIES FOR ADDITIONAL PARTICIPATION</p>

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	<p><u>DAILY STUDY COMMUNICATION</u></p> <p>During the academic year we will send you a daily text message asking whether you are currently experiencing cold or flu symptoms. We want you to promptly respond to these text messages every day, and particularly if you are experiencing new symptoms in order to facilitate rapid scheduling of a case visit if indicated, see below. In addition, we will send you short periodic emails to keep you informed about what is going on with the study and to remind you about opportunities to participate in additional parts of the study, as specified below.</p> <p><u>SMARTPHONE APP</u></p> <p>We will ask you to download and activate an app on your cell phone that tracks your location and the amount of time that 2 or more users spend together (a separate consent is required). This app, together with indoor air quality from CO₂ monitors, will help to assess and measure the exposure between persons who become sick and their contacts.</p> <p><u>CO₂ MONITOR</u></p> <p>You may also be randomly selected and asked to take a small portable CO₂ monitor home with you and to put it in your room (or to allow a research assistant working on the study to place the monitor in your room) for up to a week to help us measure and understand your environmental exposures when not in rooms with stationary monitors. If you want the monitor to stop collecting data before a week is over, you can return it early; we will retain the data collected unless you specifically request it to be deleted. In the event that you think you have lost the monitor, please notify us; you will not be charged, but can earn compensation if the monitor turns up and you return it.</p> <p><u>BASELINE SAMPLE COLLECTION AT STUDY ENTRY</u></p> <p>At the time of study entry you may be selected and invited to come to the study clinic for a baseline sample visit, where you would be asked to provide baseline nail, nasal swab, and blood samples for testing (a separate consent is required). You will be notified if you are eligible for this opportunity immediately after completing the baseline survey. If you are interested in providing samples, you will be asked to schedule an appointment for this visit and to read the baseline sample consent form, which explains in detail what you would be asked to do and the additional time involvement and compensation.</p>
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	<p><u>CASE TESTING</u></p> <p><u>IF</u> you become sick with a new respiratory illness, we want you to <u>quickly report</u> to us via one or more of the following methods: promptly reply to the daily text message, contact us by using the study email, text or call the study phone number, or visit our clinic in SPH as soon as you develop cold or flu symptoms. When you talk with us, we will ask you to describe your symptoms and time of onset, or we will ask you similar questions by text or email to determine if you are eligible for case testing; we may then invite you (as a “case”) to make an appointment that same day for a brief case visit at our study clinic in the School of Public Health or to arrange for a similar in-home/in-room visit, if you are unable to come to the clinic and study personnel are available.</p> <p>At your first study visit, study personnel will review study procedures with you and give you an opportunity to ask questions before asking you to sign an in-person version of this consent form and proceeding with the study visit. We will also measure your height and weight the first time you are seen at the study clinic.</p> <p>IF you are eligible for a brief case visit based on your symptoms and time of onset, you will be asked to complete a brief online questionnaire that contains a set of standard respiratory infection symptom questions, as well as questions about use of cold and flu medications, healthcare visits related to your illness, and recent use of the cell phone app. You will also be asked to name your 4 closest contacts over the previous 24 hours. Trained study personnel (a physician, nurse, other professional staff member, or an undergraduate research assistant under staff supervision) will measure your oral temperature using a standard thermometer and will collect 2 mid-turbinate nasal swabs to test for signs of infection.</p> <p>Prior to obtaining the nasal swabs, trained study personnel may use a small penlight to look inside your nostrils, and they will collect or will instruct and assist you (if you previously had the procedure done for this study and you wish to collect your own samples) in collecting 2 nasal swabs. These swabs will be collected in the following manner: a small, soft, contoured swab made specifically for this procedure will be inserted into your nostril until the stopper along the shaft is just outside the opening of your nose, the swab is briefly rotated, then withdrawn and placed into a collection tube. This process will be repeated with a second swab to collect a sample from inside the other nostril, unless there is an obstruction or other reason to avoid sampling, in which case 2 swabs</p>
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	<p>may be obtained from the same nostril. One swab will be used to test for a wide variety of respiratory infectious agents within approximately 24 hours to confirm that you have an infection. The other swab will be saved for a later, more detailed analysis of the infectious agents, your microbiome (microbes that typically live at the entrances to your respiratory tract), and biomarkers of infection, susceptibility, and contagiousness. We estimate it will take approximately 15-20 minutes (plus an additional 5-10 minutes if it is your first study visit) to complete the brief case visit.</p> <p>After the brief case visit, you may be selected for further in-depth case testing either later that same day or the following day, where you will be asked to answer another questionnaire and to provide additional nasal swab, blood, and exhaled breath samples. A separate consent is required for the in-depth case procedures; if you are selected you would be asked to read another consent form, which explains in detail what you would be asked to do and the additional time involvement and compensation. In addition, your contacts may be recruited to join the study (if not already enrolled) and invited to participate in contact testing (see below) to see if they develop a respiratory infection. You may be eligible to earn additional compensation, if your contacts enroll in contact testing quickly after you are tested as a case.</p> <p>Please Note: Your test results may be reported anonymously on our study website to update a summary of the numbers and types of infections detected in the study group. Many of the infectious agents we are testing for do not typically require treatment with prescription medication. We will notify you if you have an infection that should be treated and refer you to a healthcare provider. Otherwise, if you are curious to know what kind of virus we found in your swabs, you are free to call us and talk with one of the senior clinical research staff.</p> <p><u>CONTACT TESTING</u></p> <p><u>I</u>f you are identified as a close contact of a sick person, we will immediately notify you (via email, text, phone, and/or social media) and invite you (as a “contact”) to come to our study clinic in the School of Public Health for a series of up to 5 daily visits and to provide nasal swabs and blood samples for testing. A separate consent is required to participate in this part of the study; if you are eligible we will ask you to read the contact consent form, which explains in detail what you would</p>
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	<p>be asked to do, as well as the time involvement and compensation.</p> <p>STUDY COMPLETION SURVEY and/or VISIT (late Spring Semester)</p> <p>ALL study participants will be asked to complete a second baseline questionnaire near the end of the spring semester, regardless of whether or not you are tested as a case or contact during the study. You will be e-mailed a link and will be asked to complete a follow-up survey (or complete an identical questionnaire in person) to update some of the information you provided when entering the study, including time spent in your room, recent respiratory symptoms and illness, and your sleep, exercise, smoking, and alcohol habits. We estimate you should be able to complete this survey in approximately 10-15 minutes.</p> <p>IF you provide baseline samples at study entry or participate in contact or in-depth case testing (separate consent required), you will also be invited to schedule a study completion visit, where you will be asked to provide nail, nasal swab, and blood samples (see separate consent forms for details).</p> <p>PLEASE NOTE: Not everyone who joins the study will be able to provide baseline samples or to participate in the case and contact testing aspects, but some participants may have an opportunity to be tested as a case or contact more than once. As described earlier, you will be asked to review this consent form, have your questions answered, and sign it in-person at your first study visit before any samples are collected. Before participating in the baseline sample collection, in-depth case, or contact parts of the study, you will be asked to read and sign those additional specific consent forms, which fully explain what you would be asked to do. We encourage you to check the study website for general information, copies of the consent forms, and study updates such as the number of enrolled participants and the number and types of infectious agents detected within the study group. Any information posted on the website will be anonymous, with no personally identifiable information about you.</p> <p>POSSIBLE FUTURE STUDY OPPORTUNITIES</p> <p>There may be an opportunity for you to enroll in future follow-up studies, and we would like to be able to notify you if such an opportunity develops. You will be able to indicate whether or not you give</p>
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	permission for us to contact you when you sign below.
Potential Risks and Discomforts	<p>Your participation in this study may take time away from other activities or time you may have spent resting and recuperating, if you develop an ARI and participate in case testing; we will try to keep each visit as short as possible and to minimize wait times through efficient scheduling of appointments. You may not feel well while participating in the case testing part of the study due to symptoms of your illness, but participation should not exacerbate your symptoms any more than a visit to a health care provider. You may feel some embarrassment when providing information about your medical history or habits, but this will be minimized by answering the questions in a private setting on a computer or tablet. There is a small risk to your privacy and confidentiality, as we will be collecting a variety of personal data from you; we will do our best to keep your personal information confidential and limit access to only essential study personnel. All data will be transmitted between the tablet or computer used to enter the data and the server via encrypted connections and the server will be housed in a high security data center as described below under confidentiality.</p> <p>You may experience some mild pressure or discomfort, a tickling sensation, or occasional eye watering or sneezing when the nasal swabs are collected. In rare instances, swabbing inside the nose may cause very minor bleeding. If you are selected and agree to place a portable CO₂ monitor in your room, this will add a very small amount of extra weight (approximately 10 ounces) when you are transporting it back and forth from the clinic to your home and may be slightly inconvenient, but poses no other risk.</p> <p>If you schedule an in-home/in-room visit, you will be asked questions about your residence and household to confirm that a visit is feasible, and you may feel slightly uncomfortable about having study personnel come to your home. You may be asked to meet study personnel at the entrance of your building to escort them to your room, apartment, or other suitable private setting. All study personnel will have a study ID badge and will be deployed in teams of two, with at least one person of your same gender whenever possible, to minimize personal safety concerns. If you have a roommate in an on-campus residence hall, you may be required to provide us with your roommate(s) contact information so that we may obtain their permission to allow the visit to take place in your shared room, and if you wish the visit to occur in private, you may need to ask your roommate(s) or others to leave the</p>

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	<p>room or living space. During scheduling you will be asked to verify there is an acceptable place to conduct the visit and collect your samples, such as a table and chair or desk located in a well-lit uncarpeted area. There is a slight risk that surfaces in your residence could be contaminated or that personal items could be damaged in the vicinity where samples are collected. To minimize this risk, we will bring disposable coverings for the sampling area and you may be asked to clear objects from an area to enable study personnel to obtain your samples using standard sample collection procedures. In the rare instance that a spill occurs, study personnel will follow standard decontamination protocols. IF study personnel determine that your site conditions do not meet our guidelines and safety standards to conduct an in-home visit, your visit may be cancelled or terminated if already underway.</p>
Potential Benefits	<p>There are no direct benefits of participating in the baseline assessment parts of this study (answering the baseline and follow-up questionnaires, and if selected and signing separate consent, providing samples for the baseline study entry and study completion visits). However, joining the study may increase the likelihood that you will also participate in the case and contact components of this study, and possible benefits of that participation would occur if we detected that you were infected with pathogens that can and should be treated or for which early treatment may be advantageous. Although most of the pathogens that cause ARI do not require specific treatment (such as the viruses that cause common colds), we may occasionally identify pathogens that can and should be treated or for which early treatment may be advantageous. Hence, there is a small chance that, through your participation as a case or contact, you might benefit from the early detection of a treatable respiratory infection.</p> <p>We hope that, in the future, other people might benefit from this study through improved understanding of how acute respiratory infections spread and identification of biomarkers that can predict contagiousness, in order to limit the spread of respiratory infections like influenza.</p>
Confidentiality	<p>Any potential loss of confidentiality will be minimized by storing all data in an encrypted database maintained on a secure server housed in a high security data center. Only essential study personnel will have access to this data. Access to data elements will also be controlled so that only study personnel with an operational need for particular information will have access to sensitive information (for example social security numbers), and undergraduate research assistants¹ will only have access</p>

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	<p>to the clinical research database while working in the clinic or conducting scheduled in-home visits under senior staff supervision.</p> <p>If you decide to participate in the study, you will be assigned a subject ID number which will be used to access your records in the database. All biologic samples will be labeled with a unique sample ID that can only be linked to your subject ID number by Dr. Milton and his designated research study personnel.</p> <p>Collaborators within and outside the University of Maryland may conduct analyses on samples or data for research purposes, but all such samples or data will always be de-identified. If we write a report or article about this research project or post information on the study website, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law.</p> <p>The Code of Maryland Regulations (COMAR) 10.06.01.03 C, requires reporting to the Maryland Department of Health and Mental Hygiene of certain illness including personally identifiable information in the event of “any grouping or clustering of patients having similar disease, symptoms, or syndromes that may indicate the presence of a disease outbreak,” that poses a danger to public health. It also requires reporting of cases of Measles, Mumps, Pertussis and Legionellosis, which will be tested for in samples that we collect. Measles is a highly contagious virus that causes respiratory infection and rash, and Mumps is a somewhat less contagious viral illness that typically causes swollen tender salivary glands. Pertussis, also known as whooping cough, is a highly contagious bacterial respiratory infection, and Legionellosis is a bacterial infection that can cause pneumonia or flu-like illness. Measles, Mumps, and Pertussis can all be prevented through proper vaccination.</p> <p>To help us protect your privacy, we have applied for a Certificate of Confidentiality from the U.S. Department of Health and Human Services, National Institutes of Health. If approved, this Certificate will allow us to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example if there is a court subpoena. We will use the Certificate to resist any demands for information that would identify you and any of the data we collect about you except as explained below. If we obtain the Certificate, we will notify you via email.</p> <p>Any unanticipated problems involving risks to participants or others such</p>
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	<p>as unexpected or serious adverse events, non-compliance, audits, and investigation reports will be promptly reported to the University of Maryland Institutional Review Board, as well as both the U.S. Department of the Navy and Space and Naval Warfare Systems Center Pacific Human Research Protection Programs.</p>
<p>Medical Treatment</p>	<p><i>The University of Maryland does not provide any medical, hospitalization or other insurance for participants in this research study, nor will the University of Maryland provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law.</i></p>
<p>Compensation</p>	<p>BASELINE/ENROLLMENT QUESTIONNAIRE</p> <p>You will receive \$10 in your Terrapin Express account if you join the study and complete the baseline survey or questionnaire. (If you are not affiliated with the University and do not have a Terrapin Express account, you will have the option to come to the School of Public Health to obtain your compensation on a University issued debit card- see below.)</p> <p>BRIEF CASE VISIT(S)</p> <p>You will receive \$25 for each brief case visit that you are eligible for and complete (this includes a \$10 bonus for being on-time for your in-clinic appointment; for an in-home visit you will receive \$15). You have the potential to earn more if your swabs are positive for targeted pathogens (see possible additional compensation below) or if you are selected for in-depth case testing (separate consent required, see website for details).</p> <p>STUDY COMPLETION QUESTIONNAIRE</p> <p>You will receive \$10 if you complete the baseline follow-up survey or questionnaire near the end of the spring semester.</p> <p>PLEASE NOTE: You must complete the questionnaire <u>before the end</u> of the spring semester to receive this compensation.</p> <p>POSSIBLE ADDITIONAL COMPENSATION</p>

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	<p>You may also qualify for further compensation (see details below):</p> <ul style="list-style-type: none">• Each day that you promptly reply within 2 hours to the text message, you will be entered into that day’s prize drawing for up to \$20, as well as cumulative weekly prize drawings. One \$20 prize or two \$10 prizes will be awarded each day, and two \$100 prizes will be awarded each week. (Persons working on the study are not eligible for the prize drawings.)• IF you are selected and agree to place a portable CO2 monitor in your room, you will receive an additional \$10 when you return the monitor to study personnel.• IF you participate in case testing and your swabs are positive for one of the targeted pathogens, you have the potential to earn an additional \$40 BONUS if close contacts you name become enrolled in contact testing within 1 day of your case visit. (For each of the first four of your named contacts that enroll within 1 day, you will receive \$10.)• You may also earn added compensation and prizes if you download and run the smartphone app, or if you are eligible for and complete in-depth case or contact testing or provide baseline samples at study entry or study completion visits (separate consents required, please refer to study website for details). <p><i>Because you have the potential to earn more than \$100 as a research participant in this study, you must provide your name, address, and SSN to receive compensation. You will be asked to provide this information at your first study visit, or the first time you claim a prize. If you decline to provide this information you can still participate in the study, but you will not be able to receive compensation.</i></p> <p><i>You will be responsible for any taxes assessed on the compensation you receive during this study.</i></p> <p>You may choose to receive compensation payments for study visits and any bonuses or prize awards that you earn through your participation via one of two payment vehicles a) the Terrapin Express account linked to your University identification number (UID), which allows purchase at over 50 locations on campus and for which the Bursar’s Office will mail a check to your permanent address on cancellation of the account or b) a University issued debit card onto which funds will be electronically transferred. We will not make any cash payments other than by</p>
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	<p>electronic means.</p>
<p>Right to Withdraw and Questions</p>	<p><i>Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify. Your academic standing as a student or employability at UMD will not be affected by your participation or non-participation in this study.</i></p> <p>Special notice for research assistants: If you are a student working on the study and are earning course credit for your work, your grade will not be affected by your decision to participate (or not participate) as part of the study cohort.</p> <p><i>If you decide to stop taking part in the study, if you have questions, concerns, or complaints, or if you need to report an injury related to the research, please contact the investigator:</i></p> <p align="center"> Dr. Donald Milton Room 2234V SPH Building 255 University of Maryland College Park, MD 20742 Telephone: 301-405-0389 Email: dmilton@umd.edu </p>
<p>Participant Rights</p>	<p><i>If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:</i></p> <p align="center"> University of Maryland College Park Institutional Review Board Office 1204 Marie Mount Hall College Park, Maryland, 20742 E-mail: irb@umd.edu Telephone: 301-405-0678 </p> <p><i>This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.</i></p>
<p>Consent Form Quiz</p>	<p>{See attachments below to be inserted here in the electronic versions of this form.}</p>
<p>Statement of Consent</p>	<p>Your signature indicates that: you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to</p>

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	<p>participate in this research study. You will be sent a copy of this signed consent form via email, which you may print.</p> <p>Please place your initials in the appropriate box below to indicate whether we have your permission to contact you for future related studies: ____ Yes ____ No</p> <p>If you agree to participate, please type your name and, if completing in person, sign below.</p>	
<p>Signature and Date</p>	<p>NAME OF PARTICIPANT [Please Print]</p>	
	<p>SIGNATURE OF PARTICIPANT</p>	
	<p>DATE</p>	
<p>Witness/Study Personnel</p>	<p>Name [Please Print]</p>	
	<p>Date</p>	

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ATTACHMENT 1

CONSENT FORM QUIZ for online completion

[Note to IRB: if a respondent answers any of the questions incorrectly, they will be prompted to try again until selecting the correct answer before allowing the participant to type their name in the signature block]

TRUE FALSE

- 1. My participation in this research study is voluntary, and I can withdraw at any time.

- 2. If I start having new cold symptoms and I want to be tested and receive compensation as a “case” it doesn’t matter how long I take to get around to contacting the study to give samples.

- 3. I will be sent a daily text message asking whether I have cold and flu symptoms, and if I reply quickly I will be entered into daily prize drawings.

ATTACHMENT 2

CONSENT FORM QUIZ for in-person completion

[Note to study personnel: If the participant answers any of the following questions incorrectly, you must discuss these responses and review the correct answer with the participant before allowing them to sign the consent form]

- 1. I may be eligible to participate in additional parts of this study.

- 2. I will not have to give biologic samples at the study visits.

- 3. My identity as a participant will be kept confidential except as required by law.